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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet

	Complete if Known	
Application Number	10/627,358	
Filing Date	July 23, 2003	
First Named Inventor	Peter Migaly	
Art Unit	Art Unit 1614	
Examiner Name	Eric Olson	
Attorney Docket Number		

	<del>,</del>	NON PATENT LITERATURE DOCUMENTS	,
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Van Putten T. The many faces of akathisia Comprehensive psychiatry Vol 16 (1) 1975 43-47.	
		Zubenko G et al Antidepressant-related akathisia J Clin Psychopharmacol Vol 7(4) 1987 254-257.	
		Lipinski J F. et al Fluoxetine-induced akathisia: Clinical and theoretical implications.  J Clin Psychiatry 50:9 1989 339-342.)	
		Nair, NPV et al Neurochemical and receptor theories of depression. Psychiat J. Univ Ottava, vol 14(2) 1989 pp 328- 341 p 328 first column lines 3-5 and 9-10.)	
		Reeves H et al, Efficacy of risperidone augmentation to antidepressants in the management of suicidality in major depressive disorder: a randomized, double-blind, placebo-controlled pilot study.  J Clin Psychiatry 69:8 2008 1228-1236. page 1229 first column 9-10	
_		Karoum F et al Marked reduction in indexes of dopamine metabolism among patients with depression who attempts suicide. Arch Gen Psychiatry 49, 1992 447-450.  page 447 last two lines of first column and first two of second one, and p448 last four lines of second column.	
		Hirsch SR et al The concept and efficacy of the treatment of parasuicide. Br J. clin Parmac 1983, 15, 189S-194S table 1 on p. 189S.	
		Poyurovsky M et al Mirtazapine for the neuroleptic-induced akathisia. Am J psychiatry 158:5 2001 p819 second paragraph first sentence.	
		Hirose S et al. An open pilot study combining risperidone and a selective serotonin reuptake inhibitor as initial antidepressant therapy. J. Clin Psychiatry Vol 63, (8) August 2002, pages 733-736.	
		Barbee J G et al's article Lamotrigine as an augmentation agent in treatment-resistant depression.  J.Clin Psychiatry 63:8 August 2002 p 737-741.	:

Examiner Signature Date Considered				
Signature Considered	Examiner		Date	
	Signature	·	Considered	

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	(Ose as many sne	ets as m	ocessary)	Examiner Name	Eric Olson
Sheet	2	of	3	Attorney Docket Number	

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		Evins at al. Am. J. Psychiatry 156:5, May 1999 pages 798-799.	
	÷	Battaglia J et al Structured assessment and depot fluphenazine treatment of multiple suicide attempters in the emergency department. International Clinical Psychopharmacology 1999, 14: 361-372.	
		Steiner M. The neurochemistry of mood, Psychiat J. Univ Ottava, vol 14(2) 1989 pp342-343. p 342 first column lines 5-8.;	
		Montgomery SA et al Br J. clin Parmac 1983, 15, 183S-188S, p 183S second column second paragraph, and p185S first column third paragraph	
		Hirsch SR et al The concept and efficacy of the treatment of parasuicide. Br J. clin Parmac 1983, 15, 189S-194S table 1 on p. 189S.	
		Van Putten T et al Behavoral toxicity of antipsychotic drugs, J Clin Psychiatry 48 [9, Suppl]:13-19, 1987,	
<del>-</del>		Drake RE et al Suicide attempts associated with akathisia Am J Psychiatry 142:4, April 1985;	
		Shear, M.K. e al Suicide associated with akathisia and depot fluphenazine treatment. Journal of Clinical Psychopharmacology Vol. 3 (4) 1983 235-236.	
		Blum A Patients at risk of developing severe side effects from depot fluphenazine treatment Am J Psychiatry 137:2 1980 254-255.	
		Shaw ED et al A case of suicidal and homicidal ideation and akathisia in a double-blind neuroleptic crossover study J clin psychopharmacol Vol 6(3) 1986 196-197.	

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	(Use as many sne	rois as in	cossary)	Examiner Name	Eric Olson
Sheet	3	of	3	Attorney Docket Number	

	···	NON PATENT LITERATURE DOCUMENTS					
Examiner Cite Initials* No.1		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.					
		Smith WT et al. Short term augmentation of fluoxetine with clonazepam in the treatment of depression: A double-blind study. Am J Psychiatry 155:10 1998 1339-45.					
		Tsai G E. A new class of antipsychotic drugs Enhancing neurotransmission by NMDA receptors Psychiatric Times December 2008, p 16-18.	,				
		Viner MW et al Low-dose risperidone augmentation of antidepressants in nonpsychotic depressive disorders with suicidal ideation. Journal of Clinical Psychopharmacology 23:1 2003).					
		Reeves H et al Efficacy of risperidone augmentation to antidepressants in the management of suicidality in major depressive disorder: a randomized, double-blind, placebo-controlled study.  J. Clin Psychiatry 69:8 August 2008)					

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			U. S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (# known)			riguies Appear
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	Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	MM-DD-YYYY		Or Relevant Figures Appear	Ţ
	EP 0966967 A2.		Tollefson and Eli Lilly		
	EP 0958824 A2		Tollefson and Eli Lilly		
	 WO 02/053140 A2		Nesbitt and Pharmacia & Upjo	hn	Г
	EP 1238676 A1		Ralph-Pfizer		
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